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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,883	07/30/2003	Seth A. Foerster	END-897DIV2	7937

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EXAMINER	
SZMAL, BRIAN SCOTT	

ART UNIT	PAPER NUMBER
3736	

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03/16/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/630,883	FOERSTER ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 November 2009 and 30 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 24, 2009 has been entered.

Oath/Declaration

2. This application presents a claim for subject matter not originally claimed or embraced in the statement of the invention. Claim 52 is currently added. Claim 52 contains subject matter similar to the preliminary amendment filed on July 30, 2003. This amendment claims subject matter that is not fully disclosed in the current specification. In particular, the current specification is silent with respect to the preambles claiming the creation of a cavity site from which a tissue sample has been removed during a biopsy, and the claimed limitation of the implanted mass being detectable for a first time period. A supplemental oath or declaration is required under 37 CFR 1.67. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Priority

3. The Applicants claim priority to 08/308,097, filed on September 16, 1994. However, due to the fact that the above-mentioned claimed subject matter is not directly disclosed in the current specification, the current application is being treated as a Continuation-In-Part, with the effective filing date of July, 30, 2003.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation: "when the marker is disposed in a biopsy cavity created when the tissue has been removed" is not disclosed in the current specification.

6. Claims 54-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 54 discloses a method step of "removing tissue to form a biopsy cavity". The current specification fails to support this

limitation. The current specification only discloses the use of a biopsy device to place the biopsy marker at a location, not creating a cavity in tissue via the removal of a tissue sample.

7. Claims 54-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 56 and 57 disclose the use of a radiopaque marker. Claim 54 discloses the use of ultrasound to detect the marker once placed within the tissue. Claims 56 and 57, in conjunction with the disclosure of Claim 54, disclose an embodiment of the marker wherein the marker is imaged via two different imaging systems since ultrasound imaging does not use radiopaque substances to detect markers placed within tissue. Likewise Claims 61 and 62, in conjunction with Claim 58, disclose an embodiment of the marker wherein the marker is imaged via two different imaging systems since ultrasound imaging does not use radiopaque substances to detect markers placed within tissue.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 58-63 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Wolff et al (5,545,208).

Wolff et al disclose a bioabsorbable woven implantable prosthesis and further discloses all of the claimed elements of the above claims. See whole document. Even though Wolff et al is not drawn to a "biopsy marker", the claimed limitations do not differentiate the current invention over the prior art of Wolff et al, since the stent of Wolff et al is capable of performing the functions of the current claims. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 53-57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al (6,161,034) in view of Wolff et al (5,545,208).

Burbank et al disclose a means for marking a biopsy site and further disclose placing a mass or article of biodegradable material into the cavity site created by a biopsy, imaging the mass by using ultrasound, and the marker remains detectable for a first period of time after the mass is introduced into the cavity. See Column 4, lines 59-62; Column 5, lines 47-64; Column 7, lines 47-67.

Burbank et al however fails to disclose a compressed woven mass of imageable biodegradable material.

Wolff et al discloses a biodegradable, self-expandable stent and further disclose the use of a contrast media for remote imaging. See Column 6, lines 62-63; Column 7, lines 25-28 and 45-49.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the marker element of Burbank et al to use an expandable biodegradable imageable woven article, as per the teachings of Wolff et al, since it would provide a means of marking a biopsy site that can be remotely imaged as well as being palpable to relocate the biopsy site.

Response to Arguments

11. Applicant's arguments filed November 24, 2009 have been fully considered but they are not persuasive.

The Applicants have cancelled Claim 52 and added Claims 53-63, and further state Burbank et al ('034) does not constitute prior art since the earliest priority date of Burbank et al ('034) falls after the earliest priority date of the current application. The Examiner respectfully disagrees. As stated above, the claims contain claim language that was submitted in the form of a preliminary amendment at the filing of the current application. However, the claim language is not disclosed in or supported by in the specification. For instance, the current specification does not disclose any removal of tissue to create a cavity site, wherein the marker is placed in the cavity to mark the

biopsy location. The current specification is also silent with respect to any "time period" for the marker remaining detectable after introduction into tissue. If anything the current specification teaches away from any "time period". Paragraph 0001 of the PG-Publication of the current application clearly discloses "permanently defining the location", while Paragraph 0077 discloses "Biodegradable polymers and other plastics could also be used, as long as they are biocompatible, implantable, and visible using an imaging system." The current specification does not disclose whether the means for making the biodegradable polymer remotely visible as either dissipating within the tissue over time, or remaining in tissue after the material has degraded. Per Paragraph 0001, one of ordinary skill in the art can reasonably ascertain the visualizable material remains in the site permanently, even though the marker material is fully degraded.

Based on the lack of any disclosure in the current specification, and the filing of the subject matter in a preliminary amendment at the time of filing of the current application, the current application is being treated as a CIP, with a filing date of July, 30, 2003. Therefore Burbank et al ('083) constitutes prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736